



June 4, 2019

State Medical Board of Ohio  
30 East Broad St, 3<sup>rd</sup> Floor  
Columbus, Ohio 43215

Re: Opposition to Inclusion of Autism and Anxiety as Qualifying Conditions or Diseases for Treatment with Medical Marijuana

Dear Dr. Schottenstein and Members of the State Medical Board,

We, the physicians at the divisions of Child and Adolescent Psychiatry, Pediatric Neurology and Developmental Behavioral Pediatrics at Nationwide Children's Hospital are writing in opposition to a petition pursuant to Ohio Administrative Code 4731-32-05 to add autism and anxiety as a qualifying condition or disease for treatment with medical marijuana in the State of Ohio. In our view, there is little rigorous evidence that marijuana or its derivatives is of benefit for patients with autism and anxiety, but there is a substantial association between cannabis use and the onset or worsening of several psychiatric conditions.

We provide clinical care to hundreds of children with autism spectrum disorder (ASD), anxiety and intellectual delay every year. Some are highly aggressive towards themselves and others, leading to poor quality of life for themselves and their families. We appreciate the focus of the Medical Board on these chronic illnesses, and we applaud research attempts to look at the clinical effectiveness of medical marijuana in treating anxiety disorders and disruptive behaviors in children with ASD. However, we are also deeply concerned by the consideration of marijuana as a treatment for these conditions without the presence of any randomized double blind placebo controlled trial establishing the efficacy and safety of THC in this clinical population.

The development of pharmacological agents typically involves several rigorous steps, including several pre-clinical, clinical and post-clinical studies across multiple phases before consideration by the FDA for approval in clinical use. The studies cited in the petition to support the ordinance, however, meet few if any of these rigorous requirements. In fact, every other study we can find in the literature has serious methodological limitations and no placebo arm. One of the studies cited in the petition to support the use of THC in ASD is an open label trial of only 10 kids with ASD and self-injurious behavior using dronabinol as an intervention.(1) In the second study cited by the ordinance, a group of 53 children with ASD(diagnosis not confirmed by the researchers) were treated with oral



CBD oil, with improvement reported by parents at follow-up after 63 days. It is important to note that the authors themselves discuss important limitations of this

study including use of subjective report of parents to measure response, limited duration of the study of 60 days and unconfirmed diagnosis of ASD.(2)

In a retrospective study completed by Aran et al 2018, about 61% children with ASD showed improvement in disruptive behaviors. About half of the children in this study reported significant side effects from treatment and 23% discontinued the agent due to intolerable side effects.(3) In another open labelled cannabis study by Schleider et al, we were encouraged by a larger sample size of 188. However, only 30% patients with autism in this study showed significant improvement and a significant proportion (40%) of patients were excluded from this analysis leading to concerns for validity of results.

In contrast to these methodologically-questionable studies, a great deal of current evidence supports a strong association of cannabis use with unwanted outcomes:

- The onset or worsening of several psychiatric disorders, most notably psychosis and mood disorders. This is of particular concern in patients with ASD, whose emotional and communication deficits can make it difficult to report symptoms.
- A negative impact of long-term marijuana use on cognitive functions, including overall intelligence quotient, short-term memory, concentration and problem solving. These negative impacts can be devastating in a population with already-existing neurodevelopmental deficits.(5)
- A potential higher risk of obesity, in an ASD population already at risk because of picky eating habits, motor skill delays and lack of insight into making lifestyle changes.
- A gradual and persistent decline in pro-social engagement (or “amotivation syndrome”), especially problematic in an ASD population already struggling with social skills.
- A higher risk of emergency department visits due to fear and panic as a result of cannabis use (though current literature does not allow us to differentiate between anxiogenic and non-anxiogenic responses).(6)



Some short duration, open label trials have pointed towards transient improvement in anxiety symptoms. Additionally, current studies allude to decreased anxiety symptoms after a single dose. However, our clinical observation suggests families who are seeking marijuana-related treatment tend to have children with more severely affected disease and are looking for long-term treatment for aggression and self-injury.

For an agent to be considered a treatment of a chronic conditions such as clinical anxiety disorders, systematic randomized trials with multiple dosing as well as follow up phase studies are required to prove maintenance of benefits. No such studies have been completed. Although current studies point towards the role of the endocannabinoid systems in clinical anxiety disorders, consideration of plant based cannabis as a therapeutic treatment for this condition is not scientifically supported and can even be dangerous considering the implicit message it sends regarding the safety of use of marijuana in the adolescent population.(7)

Given these concerns, we respectfully request that the Board consider the following recommendations:

While we strongly support research and developmental of pharmaceutical cannabinoids and THC products for the treatment of chronic debilitating conditions, interpreting current research as indicating clinical effectiveness and safety of THC in treating conditions such as autism and anxiety disorders is of grave concerns and raises several medical, ethical and legal questions. We request the Board oppose the inclusion of autism spectrum disorder and anxiety as qualifying conditions or disease for treatment with medical marijuana in Ohio.

Respectfully,

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## References

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3. Aran A et al. "Brief Report: Cannabidiol-Rich Cannabis in Children with Autism Spectrum Disorder and Severe Behavioral Programs – A Retrospective Feasibility Study." Journal of Autism and Developmental Disorders. 2018
4. Schleider LB et al. "Real Life Experience of Medical Cannabis Treatment in Autism: Analysis of Safety and Efficacy." Nature. 9:200, 2019.
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7. Turna et al (2017). Is cannabis treatment for anxiety, mood and related disorders ready for prime time? [Depress Anxiety](#). 2017 Nov; 34 (11):1006-1017.